UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

WILMA COOLIDGE
as Executor of the Estate of Howard Southard,
deceased,

Plaintiff,

v.

DECISION & ORDER
10-CV-363S

UNITED STATES OF AMERICA,

Defendant.

I. INTRODUCTION

Plaintiff moves to preclude the testimony of Defendant's expert, Dr. David Gillespie, on the grounds that his opinions are uncertain, speculative, and lacking in foundation. (Docket Nos. 171 (Motion), 170 (Rimmler Decl.), 170-1 (Mem.)) She also moves to preclude documents relied on by Dr. Gillespie in forming his opinion, including journal articles and adverse incident reports, also called "MAUDE Reports." (Id.) The Government opposes the motion. (Docket No. 173) Before the commencement of this bench trial, Plaintiff moved for the same relief. The Court denied the motion, but allowed the parties to revisit the issue during trial. Counsel are familiar with the facts and arguments, which the Court will recite only to the extent necessary to explain its ruling. For the reasons set forth below, the Court will deny Plaintiff's motion.

II. DISCUSSION

A. Standard

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which provides in relevant part that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify" to his opinion if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702; Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596 (1993). The Rule 702 inquiry is a "flexible" one that "depends upon the particular circumstances of the particular case at issue." Floyd v. City of N.Y., 861 F. Supp. 2d 274, 286 (S.D.N.Y. 2012) (internal quotation marks omitted). Although a district court should "admit expert testimony only where it is offered by a qualified expert and is relevant and reliable," Cohalan v. Genie Indus., Inc., No. 10-CV-2415 (JMF), 2013 WL 829150, at *3 (S.D.N.Y. Mar. 1, 2013), exclusion remains "the exception rather than the rule," Floyd, 861 F. Supp. 2d at 287 (internal quotation marks omitted).

"Although expert testimony should be excluded if it is speculative or conjectural, or if it is based on assumptions that are so unrealistic and contradictory as to suggest bad faith, or to be in essence an apples and oranges comparison, other contentions that the assumptions are unfounded go to the weight, not the admissibility, of the testimony." Cohalan, 2013 WL 829150, at *5 (quoting Bacardi & Co. v. N.Y. Lighter Co., No. 97-CV-7140 (JS) (VVP), 2000 WL 298915, at *2 (E.D.N.Y. Mar. 15, 2000)); see also McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1044 (2d Cir. 1995) ("Disputes as to the

strength of [an expert's] credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony."). As the Daubert Court itself stressed, "the traditional and appropriate means of attacking shaky but admissible evidence" are not exclusion, but rather "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." Daubert, 509 U.S. at 596.

B. Analysis

1. Motion to Preclude Dr. Gillespie's Testimony

Plaintiff again moves to preclude the testimony of Dr. Gillespie on the grounds that his opinions are uncertain, speculative, and lacking in foundation. Plaintiff contends, as she did in her previous motion in limine, that Dr. Gillespie should not be allowed to testify because he does not have a definitive opinion as to the cause of Howard Southard's renal-artery blockage, and that now that "plaintiff has offered extensive evidence at trial that there was a deviation from the standard of care," Dr. Gillespie's "speculative" testimony "should not be permitted to contradict such uncontested facts." (Rimmler Decl. ¶¶ 5, 12, 26, 32).

The Court will deny Plaintiff's motion. Plaintiff's argument primarily goes to the reliability and relevance of Dr. Gillespie's opinion, as well as the information that he relied on in forming that opinion. Having reviewed the parties' submissions, including Dr. Gillespie's expert report and his deposition testimony, as well having the benefit of 15 days of trial testimony, including from the performing surgeons and from Plaintiff's expert, Dr. Muhs, the Court finds that Dr. Gillespie's opinion and the information he relied on are relevant and, under Rule 702, his specialized knowledge would help the Court further

understand the facts in issue. More specifically, the issue of whether the coverage of Howard Southard's renal arteries occurred due to operator error or another possible reason (such as the intraoperative migration of the Cook Zenith stent graft, as Dr. Gillespie will purportedly testify) is critical in determining whether there was a breach of the standard of care.

Plaintiff further argues that any testimony that Dr. Gillespie will offer concerning the possibility of stent grafts to intraoperatively migrate on their own "is not supported by the medical journal articles and the MAUDE adverse event report upon which Dr. Gillespie initially relied" and therefore must be precluded. (Rimmler Decl. ¶ 32). This argument goes to the weight to be accorded the opinions, not to their admissibility. Plaintiff will be entitled to vigorously cross-examine Dr. Gillespie at trial. See Daubert, 509 U.S. at 596; cf. McElroy v. Albany Mem'l Hosp., 332 F. Supp. 2d 502, 508 (N.D.N.Y. 2004) ("However, even if Dr. McGoldrick could point to no textual authority for her opinion, the Second Circuit has stated that disputes regarding such matters as the lack of textual authority for an expert's opinion, or faults in the methodology used by an expert in reaching an opinion, 'go to the weight, not the admissibility,' of the expert's testimony." (emphasis in original) (quoting McCullock, 61 F.3d at 1044)). Accordingly, Plaintiff's motion to exclude Dr. Gillespie's testimony is denied.

2. Motion to Preclude MAUDE Reports

Plaintiff primarily argues that the MAUDE reports should be precluded because they are statutorily inadmissible under 21 U.S.C. § 360i(b)(3), and are irrelevant "because they are not substantially similar to the instant case in their relevant details." (Mem. at 1-5; Rimmler Decl. ¶¶ 47-48)

Plaintiff's first argument regarding the statutory inadmissibility of the MAUDE reports is misplaced for two reasons. First, the statute concerns the inadmissibility of reports made by "a device user facility," which the statute defines as "a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office." 21 U.S.C. § 360i(b)(6)(A); see also id. § 360i(b)(3) ("No report made . . . by a device user facility . . . shall be admissible into evidence or otherwise used in any civil action involving private parties[.]"). None of the MAUDE reports (Docket Nos. 170-14, 170-15, 170-16, 170-17, 170-18, 170-19, 170-20, 170-21, 170-22, 170-23) relied on by Dr. Gillespie were made by a device user facility, but rather by the device manufacturer. Accordingly, this provision of the statute does not apply to the case at bar. See Smith v. I-Flow Corp., No. 09 C 3908, 2011 WL 12627554, at *1 (N.D. Ill. June 19, 2011) (denying motion in limine to preclude adverse incident reports on the same grounds); Chism v. Ethicon Endo-Surgery, Inc., No. 4:08CV00341-WRW, 2009 WL 3066679, at *1 (E.D. Ark. Sept. 23, 2009) ("Although device user facilities report to manufacturers, who then base their reports to the FDA on the user reports, § 360i does not prohibit the admissibility of manufacturer reports into evidence, or other uses of the reports in civil actions." (emphasis added)).[1]

Second, the statute explicitly prohibits such reports only "in any civil action involving private parties"; the United States of America, the Defendant in this case, is not a private party, and therefore the statute is inapplicable. Cf. Butler v. Aaron Med. Indus.,

[1] Plaintiff cites a number of cases that purportedly stand for the proposition that, in products liability cases "even mandatory Adverse Event Reports are held to be inadmissible in evidence (Mem. at 5)." In re Medtronic, Inc., 184 F.3d 807 (8th Cir. 1999); SCOX V. Medtronic, Inc., 131 F. Supp. 2d 1070 (E.D. Ark. 1999). These cases discuss the discoverability of adverse event reports, not their admissibility, and in any event, are distinguishable on the basis that they are products liability actions (not medical malpractice actions) involving private parties (not the Government).

Inc., No. C03-00896 HRL, 2004 WL 7330072, at *4 (N.D. Cal. Oct. 21, 2004) ("The reports may not be admitted into evidence or otherwise used in any civil actions involving private parties." (emphasis added) (citing H.R. Rep. No. 101-808, 1990 WL 200530)).

Plaintiff also argues that the MAUDE reports should be precluded "because they are not substantially similar to the instant case in their relevant details," relying on three products liability cases to support that proposition. See Jackson v. Firestone Tire & Rubber Co., 788 F.2d 1070, 1082 (5th Cir. 1986) ("Evidence of similar accidents occurring under substantially similar circumstances and involving substantially similar components may be probative of defective design."); Bellinger v. Deere & Co., 881 F. Supp. 813, 818 (N.D.N.Y. 1995) ("In product liability actions, it is appropriate to define the similarity of the accidents based upon the product or defect at issue."); Hyde v. Rensselaer Cty., 51 N.Y.2d 927, 929, 415 N.E.2d 972, 973 (1980) ("It is well settled that proof of a prior accident, whether offered as proof of the existence of a dangerous condition or as proof of notice thereof, is admissible only upon a showing that the relevant conditions of the subject accident and the previous one were substantially the same.").

Plaintiff does not demonstrate how these cases undermine Dr. Gillespie's reliance on MAUDE reports, which address situations where stent grafts have migrated outside of operator error—one of the key issues bearing on liability in this case. See Fed. R. Evid. R. 401; Amorgianos, 303 F.3d at 265 (evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence" (internal citations and quotation marks omitted)). Regardless, the Northern District of New York in Bellinger—upon which Plaintiff relies—concluded even that where there is a dispute as to whether

circumstances are substantially similar, "[d]ifferences in [such] surrounding circumstances go to the weight to be given the evidence, rather than to its admissibility." Bellinger, 881 F. Supp. at 818. Plaintiff will have the opportunity to vigorously cross-examine Dr. Gillespie with respect to his reliance on the MAUDE reports in forming his conclusions regarding the intraoperative migration of stent grafts.

IV. CONCLUSION

For the reasons stated above, Plaintiff's motion in limine (Docket No. 171) is denied.

SO ORDERED.

Dated: November 13, 2018
Buffalo, New York

/s/William M. Skretny
WILLIAM M. SKRETNY
United States District Judge